Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 258

Report Date:10/04/2007

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Southern Research Institute	059700307 059302007	07/10/02 04/24/00	728 729	50 (1) 50 (1)	25(680) 20(670)	510.4 484.2	1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
				Fer	nale		
Battelle Columbus Laboratory Southern Research Institute	059700307 059302007	07/11/02 04/24/00	729 731	50 (1) 50 (1)	29(695) 30(672)	337.8 319.5	1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Page: 259

Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

			Male				Female	
#All Organs: Benign Tumors		(000)				(220)		
Overall Incidence	Total	46/50 (92%) 93/100 (93%)	47/50 (94%) Mean 93%	SD 1.41%	Total	46/50 (92%) 90/100 (90%)	44/50 (88%) Mean 90%	SD 2.83%
#All Organs: Malignant Tumors		22/50 (469/)	34/50 (68%)			45/50 (200/)	22/50 (449/)	
Overall Incidence	Total	23/50 (46%) 57/100 (57%)	34/50 (68%) Mean 57%	SD 15.56%	Total	15/50 (30%) 37/100 (37%)	22/50 (44%) Mean 37%	SD 9.9%
#All Organs: Malignant and Benign Tu	ımors	50/50 (100%)	50/50 (100%)			48/50 (96%)	48/50 (96%)	
Overall Incidence	Total	100/100 (100%)	Mean 100%	SD 0%	Total	96/100 (96%)	48/50 (96%) Mean 96%	SD 0%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma		0/50 (09/)	0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	mangioma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Vehicle: ETHANOL

Route: SKIN

Length of Study: CHRONIC

Page: 260

			Male				Female	
#All Organs: Histiocytic Sarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, I Undifferentiated	Monocytic, N							
Overall Incidence	Total	17/50 (34%) 30/100 (30%)	13/50 (26%) Mean 30%	SD 5.66%	Total	10/50 (20%) 19/100 (19%)	9/50 (18%) Mean 19%	SD 1.41%
#All Organs: Malignant Lymphoma: His or Undifferentiated Cell Ty  Overall Incidence		0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Mesothelioma: Benign Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, M	alignant, NO	<b>S</b> 1/50 (2%)	1/50 (2%)	OD 04	<b></b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 000
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
fAll Organs: Mesothelioma: Malignant		0/50 (09/)	1/50 (29/)			0/50 (09/)	0/50 (09/)	
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 261

			Male				Female	
#All Organs: Osteoma		2/22 (22)	2/22 (221)			2/22 (22)	2/72 (224)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma	•							
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%
Adrenal Cortex: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

Page: 262

Male Female \*Adrenal Medulla: Hemangioma 0/50 (0%)(0%)(0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% \*Adrenal Medulla: Pheochromocytoma Benign (10%)5/50 3/50 (6%)1/50 (0%)**Overall Incidence** SD 2.83% SD 1.41% Total 8/100 (8%) Mean 8% Total 1/99 (1.01%) Mean 1% \*Adrenal Medulla: **Pheochromocytoma Complex** 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% \*Adrenal Medulla: Pheochromocytoma Malignant (0%)(8%)(0%)0/50 0/50 0/49 Mean 4% Mean 0% **Overall Incidence** Total 4/100 (4%) SD 5.66% Total 0/99 (0%) SD 0% \*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 5/50 (10%)6/50 (12%)1/50 0/49 **Overall Incidence** Total 11/100 (11%) Mean 11% SD 1.41% Total 1/99 (1.01%) Mean 1% SD 1.41% #Blood Vessel: Osteosarcoma (0%)(0%)0/50 (0%)**Overall Incidence** 0/100 (0%) SD 0% 0/100 (0%) SD 0% Total Mean 0% Total Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

Page: 263

			Male				Female	
#Bone: Chondrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Chondrosarcoma or Chond								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Chordoma		0/50 /00()	0/50 (00)		•••••	0/50 /00/	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma		0(50 (00))	0/50 (00)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 264

			Male				Female	
*Brain: Astrocytoma Malignant Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)	•••••	•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benign Overall Incidence		0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Medulloblastoma Mal Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Meningioma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Page: 265

Report Date:10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

			Male				Female	
*Brain: Meningioma: Benign, Mali	gnant, NOS	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Benig		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Maligr		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Glion	na, or Astroc		1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma		2/50 (4%)	1/50 (2%)			6/50 (12%)	2/50 (4%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	8/100 (8%)	Mean 8%	SD 5.66%
*Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date:10/04/2007

Page: 266

			Male				Female		
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (40/)	0/50 (40())			0/50 (400)	4/50 (00/)		
Overall Incidence	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	6/50 (12%) 10/100 (10%)	4/50 (8%) Mean 10%	SD 2.83%	
Clitoral/Preputial Gland: Fibrosarcoma					•••••				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Clitoral/Preputial Gland: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	•••••	•••••	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
Ear: Neural Crest Tumor		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
Esophagus: Fibrosarcoma		(201)	(00)			(0)	(00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Eye: Amelanotic Melanoma, Beni				•••••	•••••				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 267 Report Date: 10/04/2007

			Male				Female	
#Eye: Melanoma Benign Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Schwannoma Malignant	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Heart: Schwannoma Benign  Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 268

			Male				Female	
*Heart: Schwannoma Malignant		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectum: Adenoma	•••••							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectum: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum: Carcinoma or Adenoma	•••••							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Intestine Large: Colon/Rectum: Leiomyosarcoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 269

			Male				Female	
#Intestine Small: Duodenum: Leiomyoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 00/	Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/
Overall incidence	Total	0/100 (0%)	wean 0%	SD 0%	Total	0/100 (0%)	wean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma							-1	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		,				, ,	Mean 070	
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma	cified:	2/22 (221)	2/22 (22)			0/20 (00/)	2/52 (221)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall illicidence	I Otal	0/100 (070)	Wearr 070	35 0%	ı olai	0/100 (078)	Weatt 070	35 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:	2/52 (224)				2/22 (221)	2(20)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	. Otal	0,100 (070)					wican 070	
#Intestine Small: Site Unspec Leiomyoma	cified:							
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 270

			Male				Female	
#Intestine Small: Site Unspecies	fied:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		0/50 (400/)	F/F0 (400())			0/50 (00()	0/50 (0%)	
Overall Incidence	Total	6/50 (12%) 11/100 (11%)	5/50 (10%) Mean 11%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma		0/50 (00/)	0/50 (404)			0/50 (00()	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma		6/50 (12%)	7/50 (14%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 1.41%	Total	0/30 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transition Carcinoma	al Epitheliu	m:			•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Pelvis and Transition Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System** Tumor Incidence for Selected Control Animal Groups

Vehicle: ETHANOL

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 271

			Male				Female	
Kidney: Pelvis and Transition	al Epitheliu	m:						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma		4/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%)	0/50 (0%)	CD 4 440/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence	I Ulai	0/100 (0%)	Wearr 0%	30 0%	I Ulai	0/100 (0%)	iviean 0%	3D 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		(22)	2(-2 (22)			2/22 (221)	(201)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overali incidence	Total	1/100 (1%)	weari 1%	SD 1.41%	TOlai	0/100 (0%)	wean 0%	3D 0%
*Kidney: Renal Tubule: Hemangiosarcoma		0(50 (004)	2/52 (224)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overan microence	I Ulai	0/100 (0/0)	IVICALI U/0	3D 070	IUIAI	0,100 (0.76)	IVICALI U/0	30 0/0
*Kidney: Renal Tubule: Lipoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

> Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Page: 272

			Male				Female	
*Kidney: Renal Tubule: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benign		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma		0/50 (00/)	0/50 (00/)			0/50 (001)	0/50 (001)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Cholangiocarcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma		0/50 (0%)	0/50 (0%)			0/50 /00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 273

Report Date: 10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Liver: Hemangiosarcoma		0/50 (00/)	0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		0/50 (00()	0/50 (00)			0/50 /00/)	0/50 (400/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 6/100 (6%)	6/50 (12%) Mean 6%	SD 8.49%
*Liver: Hepatocellular Carcinoma		4/50 (20()	0/50 (00/)			0/50 (00/)	0/50 (09/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatob		0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatoc	ellular Adenoma 1/50 (2%)	0/50 (0%)		•••••	0/50 (0%)	6/50 (12%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	6/100 (6%)	Mean 6%	SD 8.49%
*Liver: Hepatocellular Carcinoma Hepatoblastoma	, Hepatocell				•••••			
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 6/100 (6%)	6/50 (12%) Mean 6%	SD 8.49%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Page: 274

Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

			Male				Female	
*Lung: Alveolar/Bronchiolar Ad	denoma	1/50 (2%)	1/50 (2%)			4/50 (8%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 5.66%
*Lung: Alveolar/Bronchiolar Ca	arcinoma	1/50 (2%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Lung: Alveolar/Bronchiolar Ca Adenoma	arcinoma or Alv		4/50 (20/)			4/50 (99/)	0/50 (00/)	
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	4/50 (8%) 4/100 (4%)	0/50 (0%) Mean 4%	SD 5.66%
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Lung: Squamous Cell Carcino	ma	0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 275

			Male				Female	
#Lymph Node, Mesenteric: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		, ,				,		
#Mammary Gland: Adenoma		0/50 (00/)	0/50 (001)			4/50 (00/)	0/50 (00/)	
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	1/50 (2%)	0/50 (0%)	CD 4 440/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	05.00/		2/50 (4%)	4/50 (8%)	00.000/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	6/100 (6%)	Mean 6%	SD 2.83%
Mammary Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			3/50 (6%)	4/50 (8%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	7/100 (7%)	Mean 7%	SD 1.41%
Mammary Gland: Fibroadenoma								
		1/50 (2%)	0/50 (0%)			14/50 (28%)	12/50 (24%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	26/100 (26%)	Mean 26%	SD 2.83%
Mammary Gland: Fibroma								
	<b>.</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/	<b>+</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Overall Incidence

Rhabdomyosarcoma

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

			Male				Female	
Mammary Gland: Fibroma, Fibroadenoma	or Adenoma	4/50 (00/)	0/50 (00/)			45/50 (200)	40/50 (040/)	
verall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	15/50 (30%) 27/100 (27%)	12/50 (24%) Mean 27%	SD 4.24%
Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, c	or <b>Adenoma</b> 1/50 (2%)	0/50 (0%)			17/50 (34%)	14/50 (28%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	31/100 (31%)	Mean 31%	SD 4.24%
Mesentery: Fibrosarcoma		0/50 /0%	0/50 (00/)			0/50 (00()	0/50 (00/)	
verall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
lesentery: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
lesentery: Osteosarcoma	•••••							
verall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

Total

0/50

0/100 (0%)

(0%)

0/50

(0%)

SD 0%

Mean 0%

Page: 276

Report Date: 10/04/2007

Total

0/50

0/100 (0%)

(0%)

(0%)

SD 0%

......

Mean 0%

0/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Page: 277

			Male				Female	
*Nose: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Chondroma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Sarcoma		0/50 (00/)	0/50 (00/)			0/50 /00/	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Squamous Cell Carcinom	na	0/50 (0%)	1/50 (2%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or I	ongue, Phary	, ,			•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinom	ongue, Phary	nx, Tooth, Gingiva):					•••••	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 278

Report Date: 10/04/2007

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** (0%)0/50 (0%)3/50 (6%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 3/100 (3%) Mean 3% SD 4.24% #Oral Mucosa: Squamous Cell Carcinoma 0/50 (0%)(0%)0/50 1/50 (2%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 1/100 (1%) Mean 1% SD 1.41% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)(0%)SD 0% SD 0% Overall Incidence Total 0/100 (0%) Mean 0% Total 0/100 (0%) Mean 0% **Granulosa Cell Tumor Benign** 0/50 0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% \*Ovary: **Granulosa Cell Tumor Malignant** (0%)Mean 0% SD 0% Overall Incidence Total 0/100 (0%) \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Page: 279

			Male				Female	
*Ovary: Granulosa-Theca Tumor Bo	enign					2/22 (221)	2(-2)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Adenoma								
Overall Incidence	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma		0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Parathyroid Gland: Adenoma								
Overall Incidence	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/46 (0%) 0/91 (0%)	0/45 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 280

			Male				Female	
#Peripheral Nerve: Schwannoma Malignant		2/52 (221)	2/52 (221)			(201)	2/22 (221)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence		, ,				` ,		
#Peripheral Nerve: Schwannoma: Benign, Malig	ınant, NOS	<b>;</b>						
3,	,	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
						•••••		
*Pituitary Gland: Pars Distalis or Adenoma	r Unspecit		00(50 (500))			05/50 (700/)	00/50 (000/)	
O	T-1-1	32/50 (64%)	29/50 (58%)	OD 4.040/	T-1-1	35/50 (70%)	33/50 (66%)	OD 0.000/
Overall Incidence	Total	61/100 (61%)	Mean 61%	SD 4.24%	Total	68/100 (68%)	Mean 68%	SD 2.83%
*Pituitary Gland: Pars Distalis or Carcinoma								
Garomoma		0/50 (0%)	5/50 (10%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 7.07%	Total	3/100 (3%)	Mean 3%	SD 4.24%
*Pituitary Gland: Pars Distalis or Carcinoma or Adenoma	r Unspecif	ied Site:						
		32/50 (64%)	34/50 (68%)			35/50 (70%)	36/50 (72%)	
Overall Incidence	Total	66/100 (66%)	Mean 66%	SD 2.83%	Total	71/100 (71%)	Mean 71%	SD 1.41%
*Pituitary Gland: Pars Intermedia Adenoma								
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 281

Report Date:10/04/2007

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Pituitary Gland: Pars Interme Carcinoma	edia:							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma		0/50 (0%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		0/50 (00/)	4/50 (20()					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Salivary Glands: Sarcoma		0/50 (00)	4/40 (00/)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Report Date: 10/04/2007

Page: 282

			Male				Female	
#Skeletal Muscle: Fibrosarcoma		0/50 (00/)	0/50 (00)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma			0/50 (00)					•••••
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Lipoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma or R	thabdomyoma		0/50 (00/)			4/50 (00()	0/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Page: 283

Report Date:10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

			Male			0/50 (0%) 0/50 (0%) tal 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) tal 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) tal 0/100 (0%) Mean 0% SD 0%		
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	` ,	` ,	SD 0%
#Skin: Basal Cell Adenoma								
Buour Com Audinomia		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:			•••••				• • • • • • • • • • • • • • • • • • • •	
Basal Cell Adenoma or Ba	sosquamou		0/50 (00/)			2/22 (22/)	2(22 (22)	
Overell besidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` ,	` ,	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	,		
Skin: Basal Cell Adenoma, Base Trichoepithelioma	osquamous '	Tumor Benign, or						
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma							•••••	
		0/50 (0%)	0/50 (0%)			` ,	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	,		
Skin: Basal Cell Carcinoma or E NOS)								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**OII.** OCI2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

ute: SKIN

Page: 284

			Male				Female	
#Skin: Basal Cell Carcinoma, Tumor (benign, maligi								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar	inoma, Carcinor oma, Adenoma,	na, Basosq. Tumor (M Papilloma, Sq pithelioma						
Overall Incidence	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#Skin: Fibroma		7/50 (14%)	5/50 (10%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcom Fibrous Histiocytoma	na, Sarcoma, My	xoma, Myxosarcoma, o				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
≴Skin: Fibrosarcoma, Sarcon Histiocytoma	na, Myxosarcom	•						
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 285

			Male				Female	
#Skin: Fibrous Histiocytoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma	• • • • • • • • • • • • • • • • • • • •	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma	•••••	2/50 (4%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Lipoma	••••							
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Page: 286

Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

			Male				Female	
#Skin: Neural Crest Tumor		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwa	ınnoma benign		0/50 /00/			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Neurofibrosarcoma or S			2/50 (4%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Skin: Neurofibrosarcoma, Nemalignant or NOS)	urofibroma, or	, -						
Overall Incidence	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Skin: Osteosarcoma		0/50 (00)	0/50 (00/)				0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

Page: 287

			Male				Female	
#Skin: Schwannoma Benign		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
Skin: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
∜Skin: Squamous Cell Carcinoma, Basosquamous Tumor (mal			0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Squamous Cell Papilloma o	r Papillom	<b>a</b> 0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

Page: 288

			Male				Female	
#Skin: Squamous Cell Papilloma, Carcinoma or Keratoacant		Squamous Cell						
		2/50 (4%)	4/50 (8%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 0%
#Skin:			•••••	•••••		•••••		
Squamous Cell Papilloma,	Papilloma,	or Keratoacanthoma 2/50 (4%)	4/50 (8%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Trichoepithelioma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma						-/	- ()	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (09/)	1/50 (20/)			0/50 /0%\	0/50 /09/	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Jveran meluence	i Otai	1/100 (1/0)	IVICALL 170	30 1.41/0	i Otal	0/100 (0/0)	IVICALI U/0	3D 070

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Page: 289

			Male				Female	
#Spinal Cord: Astrocytoma Benign	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 004
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma		0/50 (00()	0/50 (00/)			0/50 //0//	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Report Date:10/04/2007

Page: 290

Species: RATS Strain: F344

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male		Female
#Stomach, Forestomach: Schwannoma Malignant		0/50 (00/)	0/50 (00/)	0/50 /6	0/50 /00/)
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD (	•	0%) 0/50 (0%) Mean 0% SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0	0%) 0/50 (0%)
Overall Incidence	Total	0/100 (0%)	Mean 0% SD (	,	, ,
#Stomach, Forestomach: Squamous Cell Carcinoma c			1/50 (2%)	0/50 (0	0%) 0/50 (0%)
Overall Incidence	Total	2/100 (2%)	Mean 2% SD (	,	
#Stomach, Forestomach: Squamous Cell Papilloma		1/50 (2%)	1/50 (2%)	0/50 (0	0%) 0/50 (0%)
Overall Incidence	Total	2/100 (2%)	Mean 2% SD (	*	, ,
#Stomach, Glandular: Leiomyosarcoma		0/50 (00/)	0/50 /00/	2/52 /6	2/52 (201)
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD (	*	0%) 0/50 (0%) Mean 0% SD 0%
#Stomach, Glandular: Lipoma					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD (	*	0%) 0/50 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Contract/Lab: All Laboratories

# **Toxicology Data Management System**

Vehicle: ETHANOL

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Strain: F344 Length of Study: CHRONIC Page: 291

			Male				Female	
*Testes: Adenoma								
Overall Incidence	Total	37/50 (74%) 73/100 (73%)	36/50 (72%) Mean 73%	SD 1.41%				
*Thymus: Sarcoma		0/49 (0%)	0/49 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/45 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/49 (0%)	0/49 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/43 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/40 (001)	0/40 (00/)			0/45 (00/)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig	nant, NOS	0/49 (0%)	0/49 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Adenoma		40/50 (00%)	5/50 (4.00V)			0/50 /400()	0/50 (00/)	
Overall Incidence	Total	10/50 (20%) 15/100 (15%)	5/50 (10%) Mean 15%	SD 7.07%	Total	8/50 (16%) 11/100 (11%)	3/50 (6%) Mean 11%	SD 7.07%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 292

			Male				Female	
*Thyroid Gland: C-Cell: Carcinoma		2/50 (4%)	5/50 (10%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 4.24%	Total	2/100 (2%)	Mean 2%	SD 2.83%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		12/50 (24%)	10/50 (20%)			8/50 (16%)	5/50 (10%)	
Overall Incidence	Total	12/50 (24%) 22/100 (22%)	Mean 22%	SD 2.83%	Total	8/50 (16%) 13/100 (13%)	5/50 (10%) Mean 13%	SD 4.24%
*Thyroid Gland: Follicular Cell: Adenoma	•••••	0/50 (0%)	4/50 (20/)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		4/50 (00/)	4/50 (00)			0/50 (00/)	4/50 (00/)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Tissue NOS: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 293

			Male				Female	
#Tissue NOS: Leiomyoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Paraganglioma		0/50 (00()	0/50 (00/)		•••••	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Liposarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Page: 294

Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

			Male				Female	
#Tongue: Squamous Cell Carcinoma	or Papillom		0/50 (00/)			0/50 (00/)	0/50 (400)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Tooth: Odontoma		0/50 (00/)	0/50 (00/)			4/50 (00/)	0/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Urinary Bladder: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma		0/50 (0%)	0/50 (00/)			0/50 (00/)	0/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma		0/50 (004)	0/50 (00/)			0/50 (00/)	0/50 (004)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 295

Report Date:10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Urinary Bladder: Papilloma		2/72 (221)	2/72 (224)			2/52 (221)	2/22 (221)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Hemangioma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
<i>m.</i> ,		• • • • • • • • • • • • • • • • • • • •				•••••		
#Uterus: Hemangiosarcoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 296

	Male			Female	
#Uterus: Leiomyoma			(00)	(201)	
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Uterus: Polyp Stromal				•••••	
Overall Incidence		Total	2/50 (4%) 12/100 (12%)	10/50 (20%) Mean 12%	SD 11.31%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus:				•••••	
Sarcoma Stromal or Polyp Stromal Overall Incidence		Total	3/50 (6%) 13/100 (13%)	10/50 (20%) Mean 13%	SD 9.9%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina:					
Polyp Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

n: Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

Page: 297

			Male				Female	
#Vagina: Sarcoma						0/50 (00/)	0/50 (00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#7. make allo Oleve de						• • • • • • • • • • • • • • • • • • • •		
#Zymbal's Gland: Adenoma		(224)	2/22 (22()			0.70	2/22 (22()	
	<b>.</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>+</b>	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma				•••••		•••••	•••••	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#7balla Claudi								
#Zymbal's Gland: Carcinoma or Adenoma								
caronicina of Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied